

POSACONAZOLE 40 mg/ml Oral Suspension

Posaconazole

Consumer Medicine Information (CMI)

What is in this leaflet

Please read this leaflet carefully before you start using POSACONAZOLE Oral Suspension.

This leaflet answers some common questions about POSACONAZOLE Oral Suspension. It does not contain all the available information. It does not take the place of talking to your doctor, nurse or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking POSACONAZOLE Oral Suspension against the benefits he/she expects it will have for you.

If you have any concerns about taking POSACONAZOLE Oral Suspension, ask your doctor, nurse or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What POSACONAZOLE Oral Suspension is used for

POSACONAZOLE Oral Suspension are used for:

- The treatment of invasive aspergillosis, a fungal infection caused by a fungus called aspergillus
- The treatment of some other serious fungal infections called fusariosis, cryptococcosis, zygomycosis, chromoblastomycosis and mycetoma.

POSACONAZOLE Oral Suspension is also used for:

- The treatment of fungal infections in the mouth and throat caused by Candida, such as oral thrush, and the more serious systemic infection called candidemia.

Treatment of these serious fungal infections with POSACONAZOLE is usually reserved for patients who do not respond to or cannot tolerate other medicines used to treat these types of fungal infections.

POSACONAZOLE is also used to treat coccidioidomycosis, a rare and serious fungal infection.

These types of serious fungal infections usually occur in some patients who may have lowered resistance to infection due to poor immunity.

POSACONAZOLE is also used to prevent fungal infections, such as yeasts and moulds, from occurring in patients who are at high-risk of developing these infections.

POSACONAZOLE is a medicine which belongs to the triazole group of antifungal medicines.

POSACONAZOLE works by killing or stopping the growth of the fungi causing these infections.

Your doctor may have prescribed POSACONAZOLE Oral Suspension for another reason.

Ask your doctor if you have any questions about why POSACONAZOLE Oral Suspension has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you take POSACONAZOLE Oral Suspension

When you must not take POSACONAZOLE Oral Suspension

Do not take POSACONAZOLE if:

1. You have an allergy to:

- posaconazole or any other triazole antifungal medicines
- any of the ingredients listed at the end of this leaflet (See Product Description)

Symptoms of an allergic reaction may include skin rash, itching, hives, shortness of breath, difficulty breathing, swelling of the face, tongue or other parts of the body.

2. You are pregnant or may become pregnant

Do not take POSACONAZOLE if you are taking any of the following medicines:

- halofantrine, a medicine used to treat malaria
- simvastatin, lovastatin, atorvastatin or similar medicines (called HMG-CoA reductase inhibitors or statins) that are used to treat high cholesterol levels.
- certain medicines used to treat allergy or hay fever (terfenadine or astemizole)
- cisapride, a medicine used to treat certain stomach problems
- pimozide, a medicine used to treat certain mental disorders
- quinidine, a medicine used to treat irregular heart beat
- Ergotamine and dihydroergotamine, which are medicines used to treat migraine

POSACONAZOLE is not recommended for children below the age of 13 years.

Talk to your doctor, nurse or pharmacist if you have any questions about this information.

Do not take POSACONAZOLE if the packaging is torn or shows signs of tampering.

Do not take POSACONAZOLE after the expiry date (Exp.) stamped on the pack. If you take this medicine after the expiry date has passed, it may not work as well. Return this medicine to your pharmacist for disposal if it has expired or is damaged.

If you are not sure whether you should start using POSACONAZOLE Oral Suspension, talk to your doctor.

Before you start to take POSACONAZOLE Oral Suspension

Tell your doctor if:

1. You have any allergies to any other medicines, especially other antifungal medicines such as itraconazole, fluconazole, voriconazole, ketoconazole or any other substances such as foods, preservatives or dyes.

2. You have or have ever had any other health problems/ medical conditions including:

- any kidney problems
- any liver problems
- any heart problems

Follow your doctor's advice if any blood tests to check on your kidney or liver are recommended.

3. You are pregnant or plan to become pregnant

POSACONAZOLE should not be taken during pregnancy unless indicated by your doctor. Women who are of childbearing potential should use effective contraception while taking POSACONAZOLE. Your doctor can discuss the risks and benefits.

4. You are breastfeeding

POSACONAZOLE should not be taken by breastfeeding women. It is possible that the active ingredient, posaconazole, may be passed into the breast milk. Your doctor can discuss the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you take POSACONAZOLE Oral Suspension.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may interfere with POSACONAZOLE. These include:

- Warfarin, a medicine used to prevent blood clots
- Rifabutin, a medicine used to treat tuberculosis
- Phenytoin, a medicine used to treat fits or convulsions
- Cimetidine, a medicine used to treat stomach ulcers; also proton-pump inhibitors such as omeprazole used to treat stomach disorders (applies only to POSACONAZOLE Oral Suspension).
- Vinca alkaloids, used in the treatment of cancer
- Ciclosporin, tacrolimus and sirolimus, used to treat certain immune system problems or to prevent organ transplant rejection
- Midazolam and other benzodiazepine medicines used to treat anxiety or sleeplessness
- HMG-Co-A reductase inhibitors such as simvastatin, lovastatin and atorvastatin, which are used to lower cholesterol
- Calcium channel blockers, such as diltiazem, nifedipine and verapamil, used in certain heart conditions and to lower blood pressure
- Anti-retroviral medicines, such as efavirenz, atazanavir and ritonavir, used in the treatment of HIV.
- Digoxin, used to treat certain heart conditions

These medicines may be affected by POSACONAZOLE or may affect how well it works. You may need different amounts of your medicine or you may need to take different medicines. Your doctor will advise you.

Tell your doctor, nurse or pharmacist if you are taking any other medicines, including any medicines you buy without a prescription from a pharmacy, supermarket or health food shop (for example St John's Wort).

How to take POSACONAZOLE Oral Suspension

Follow all directions given to you by your doctor, nurse and pharmacist carefully. They may differ from the information in this leaflet.

If you do not understand the instructions below, ask your doctor, nurse or pharmacist for help.

Children

POSACONAZOLE Oral Suspension is not recommended for children or adolescents below the age of 18 years for treatment of invasive fungal infections.

In high risk patients aged 13 years and older, POSACONAZOLE may be given to prevent the development of invasive fungal infections.

How much POSACONAZOLE to take

Treatment of invasive fungal infections (aspergillosis, oesophageal candidiasis, candidemia, coccidioidomycosis, fusariosis, cryptococcosis, zygomycosis, chromoblastomycosis, and mycetoma): The usual dose for adults is 10 ml twice a day.

Prevention of invasive fungal infections: The usual dose for adults is 5 ml 3 times a day.

Treatment of oropharyngeal candidiasis: The usual dose for adults is 5 ml once on the first day, then 2.5 ml once a day for the next 13 days.

Treatment of refractory oropharyngeal candidiasis: The usual dose for adults is 10 ml twice a day

Shake the bottle well before use. A syringe is supplied with the medicine.

The dose may vary from one patient to another. Your doctor may recommend a different dose depending on your condition.

How to take POSACONAZOLE Oral Suspension

Shake the bottle well before use.

You should take POSACONAZOLE Oral Suspension with a meal or a nutritional supplement. Taking this medication with food containing fat will improve absorption.

When you use the medicine follow the instructions below:

1. Shake the bottle well.
2. Remove the bottle cap and push the adaptor firmly into the top of the bottle and leave in place for future doses.
3. Push the tip of the dosing syringe into the hole in the adaptor.
4. Turn the bottle upside down.
5. Pull the plunger of the syringe back so that the medicine is drawn from the bottle into the syringe. Pull the plunger back to the point on the scale that corresponds to the dose prescribed.
6. Turn the bottle back the right way up and carefully remove the syringe from the adaptor, holding it by the barrel rather than the plunger.
7. Gently put the tip of the syringe into your mouth and to the inside of your cheek.
8. Slowly and gently push the plunger down to gently squirt the medicine into the inside of your cheek and swallow it. Do not forcefully push down the plunger, or squirt the medicine to the back of your mouth or throat, as you may choke.
9. Remove the syringe from your mouth.
10. Put the cap back on the bottle with the adaptor left in place.
11. Wash the syringe with warm water and rinse well. Hold the syringe under water and move the plunger up and down several times to make sure the inside of the syringe is clean. Let the syringe air dry completely before you use it again for dosing. Store the syringe in a hygienic place with the medicine.

Directions for opening the bottle

POSACONAZOLE Oral Suspension comes with a child-resistant cap. It can be opened by pushing down on the plastic screw cap while turning it anti-clockwise.

How long to take POSACONAZOLE Oral Suspension

Your doctor will advise how long you should take POSACONAZOLE Oral Suspension.

Continue taking POSACONAZOLE Oral Suspension for the length of time that your doctor recommends.

If you forget to take it

Take the dose you missed as soon as you remember, then continue to take it as you normally would.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you have missed.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

While you are taking POSACONAZOLE Oral Suspension

Things you must do

Always follow your doctor's instructions carefully.

- If you are a woman of childbearing age, talk to your doctor about the need for effective contraception. Once you have finished taking POSACONAZOLE, continue using contraception until your next period.
- If you become pregnant while you are taking POSACONAZOLE, tell your doctor immediately.
- If you are about to start any other new medicine, tell your doctor that you are taking POSACONAZOLE.
- If you need to have any blood tests, tell your doctor you are using POSACONAZOLE. POSACONAZOLE may affect the results of some laboratory tests.

Tell all doctors, dentists and pharmacists who are treating you that you are taking POSACONAZOLE.

Things you must not do

- Do not give POSACONAZOLE to anyone else, even if they have the same condition as you.
- Do not use POSACONAZOLE to treat any other medical complaints unless your doctor tells you to.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much POSACONAZOLE Oral Suspension.

Do this even if there are no signs of discomfort or poisoning.

Side effects

Tell your doctor as soon as possible if you have any problems while taking POSACONAZOLE Oral Suspension, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you experience any of the following:

- Loss of appetite
- Sleeplessness
- Headache, dizziness, sleepiness
- Tingling in fingers or toes
- Hot flushes
- Upset stomach, nausea, vomiting, stomach pain, diarrhoea, gas from stomach or bowel, dry mouth, altered sense of taste.
- Dry skin, rash, itchiness
- Back pain
- Fever

If any of the following happen, stop taking POSACONAZOLE and tell your doctor immediately or go to casualty at your nearest hospital:

- rash, itchiness, hives
- swelling of the face, lips, mouth, throat or neck which may cause difficulty swallowing or breathing
- tingling or numbness of the hands or feet, or muscle weakness

These are very serious side effects. You may need urgent medical attention. These side effects are rare.

Tell your doctor, nurse or pharmacist if you notice anything that worries you or that is making you feel unwell, even if it is not on this list.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

After taking POSACONAZOLE Oral Suspension

Storage

Keep POSACONAZOLE Oral Suspension in the bottle until it is time to take it.

Keep POSACONAZOLE Oral Suspension in a cool dry place where the temperature stays at or below 25°C. Do not freeze.

Do not store POSACONAZOLE or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep POSACONAZOLE and all other medicines where children cannot reach them.

A locked cupboard at least one-and-a-half meters above the ground is a good place to store medicines.

Disposal

Ask your pharmacist what to do with any medicine that is left over, or if the expiry date has passed.

Product description

What it looks like

POSACONAZOLE Oral Suspension is white to off-white homogenous suspension, free from foreign matter with cherry odour.

It is supplied as 105 ml of oral suspension in a 125 ml amber glass bottle with a child-resistant cap and contains a 5 ml dosing syringe (polypropylene/polyethylene) with 0.5 ml graduation marks and an adaptor for the syringe (polyethylene) for measuring 2.5 and 5 mL doses of the oral suspension.

Ingredients

Active ingredient:

POSACONAZOLE Oral Suspension contains 40 mg posaconazole (the active ingredient) per ml of suspension.

Inactive ingredients:

The other ingredients of POSACONAZOLE Oral Suspension are Polysorbate 80, Xanthan gum, Sodium benzoate (E 211), Citric acid monohydrate, Sodium citrate, Glycerol, Liquid glucose, Titanium dioxide (E 171), Simethicone emulsion 30%, Artificial cherry flavour, Purified water.

If you have been told by your doctor that you have an intolerance to certain sugars (for example, lactose), tell your doctor before taking POSACONAZOLE Oral Suspension.

Sponsor

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